

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION

MDL NO.
2:12-MD-02327

THIS DOCUMENT RELATES TO:

CAROLYN LEWIS

CIVIL ACTION NO.
2:12-cv-04301

February 12, 2014
Charleston, WV

TRANSCRIPT OF TRIAL - DAY 3
BEFORE THE HONORABLE **JOSEPH R. GOODWIN**,
UNITED STATES DISTRICT JUDGE, AND A JURY

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1 to try to get the test to come out right. And if you've used
2 up too much particle, you may not get to the next six because
3 you don't have any left.

4 THE COURT: So on some of these samples you ran six
5 standardized tests. On some of these samples you ran fewer
6 than that because of an insufficient amount of material to
7 complete the test.

8 MR. ANDERSON: Because of the nature of destructive
9 testing of polymers.

10 THE COURT: Give me an idea of how many you ran six
11 tests on and how many you ran less tests on.

12 MR. ANDERSON: I have two binders this big, Your
13 Honor, and so I would have to go through here and try to pull
14 all those out. It's twenty-four samples and six tests.

15 THE COURT: Well, 24 -- I excluded in Dr. Klinge's
16 thing, the report didn't provide any information about how he
17 obtained the particular samples.

18 Here this morning you're providing me with an explanation
19 of how he selected them, but I would like the answer to this,
20 to me an important question. How are we to know that the
21 large samples are representative of explants, that is to say,
22 that there's a scientific and reliable basis for concluding
23 that 23 out of dozens or more is a representative sample?

24 MR. ANDERSON: Your Honor, the best that we could do
25 is try to collect explants that were available. We took every

1 one that we could. We looked at every one of them, and we had
2 all of that analysis in these books and that he deposed him
3 on. We left no test out that was done. And of those, some of
4 them showed degradation, some did not. They're all explanted
5 and the same battery of tests are done on polypropylene. So
6 it is more of an objective test than a subjective test.

7 In order to determine whether or not -- what the
8 denominator is, if that's what you're looking for, Your Honor,
9 the only way to look at the denominator is -- I'm sure they'll
10 point out on cross-exam of one of our witnesses, "Well, this
11 has been in hundreds of thousands of women and it doesn't
12 degrade in all of them." No, but we have a representative
13 sampling --

14 THE COURT: How do we know it's representative?
15 That's my question. The only criteria that you've given me is
16 not an indicator of representation. That is to say, you
17 selected only samples -- and I grant you, they're the only
18 ones you could get -- that were big enough. I don't know that
19 because the sample was big enough shows that it's
20 representative of explants.

21 MR. ANDERSON: By way of example, Your Honor, an
22 analogy. Dr. Klosterhalfen on behalf of Ethicon has a
23 database of explants, okay? Some of those explants, you can
24 determine whether or not there was fibrotic bridging. Some
25 you can't, because they weren't big enough. Some you can

1 determine whether or not there was scar plating. Some you
2 can't because they weren't big enough or not a good enough
3 sample.

4 What you do is you collect what you can and you do an
5 analysis of those. And within the number that you have, you
6 can make some determination as to, okay, out of this
7 representative sampling of explants --

8 THE COURT: The problem is the representative part.
9 That's what I'm trying to figure out with regard to *Daubert*
10 and *Kumho Tire*, is was there a scientific methodology used to
11 show that this is a representative sample.

12 In other words, if the only people I could find that had
13 malaria were people that were in a malaria ward at a hospital,
14 they would not be necessarily representative of everybody in
15 the world that had malaria. As I think I pointed out -- and
16 I'll say it again -- my analogies are always terrible, but go
17 ahead.

18 MR. ANDERSON: I would say that, you know, Your
19 Honor, they're welcome to point this out on cross-examination,
20 but the only way to get explants is when they come out of
21 women. You can't go and affirmatively take them out and just
22 say we're going to take these out of healthy women and we're
23 going to take these out of unhealthy women and we're going to
24 compare it so that we have a denominator of all of the healthy
25 explants with the unhealthy explants.

1 THE COURT: Okay. What's your expert on
2 polypropylene going to say with regard to examining explants,
3 if at all?

4 MR. THOMAS: Your Honor, my expert only has looked
5 at the Carolyn Lewis explant.

6 THE COURT: That's all I need to hear. Your expert
7 is qualified to offer, as I understand it, without objection,
8 opinions about polypropylene degradation; is that correct?

9 MR. THOMAS: Correct, Your Honor.

10 THE COURT: And he may also offer opinions related
11 to the degradation, if any, of Miss Lewis's explant. He's not
12 a doctor. Neither he nor your polypropylene expert, absent a
13 medical degree or a qualification in that regard, may talk
14 about the effects of polypropylene in the human body. Is that
15 clear enough?

16 All right. Let's give you -- we're almost five minutes
17 till the jury comes in. I'm sure you need time to straighten
18 your desk out. Yes, sir?

19 MR. THOMAS: I don't think you addressed the
20 ultimate question, Your Honor, whether Dr. Jordi will be
21 permitted to talk about the additional explants.

22 THE COURT: No --

23 MR. THOMAS: Thank you.

24 THE COURT: -- he may not.

25 MR. ANDERSON: What if we voir -- what if I offer to

1 CERTIFICATE OF OFFICIAL REPORTERS

2
3 Teresa M. Ruffner and Harold M. Hagopian do hereby
4 certify that the foregoing is a true and correct
5 transcript, to the best of our abilities, from the record
6 of proceedings in the above-entitled matter.
7

8 s/Teresa M. Ruffner
9 Reporter

February 12, 2014
Date

10 s/Harold M. Hagopian
11 Reporter

February 12, 2014
Date
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